GE200 BLOOD GLUCOSE TEST STRIP INSERT

Intended Use

The GE200 Blood Glucose Monitoring Systems is to be used by:

- Any person with diabetes, for monitoring their glucose levels in capillary whole blood (CB) from the fingertip, palm and forearm;
- A single user to aid in the management of diabetes at home.
- The GE200 Blood Glucose Monitoring System is not intended to be used for diagnosis of, or screening for diabetes or for neonatal use.

GE200 Blood Glucose Test Strips:

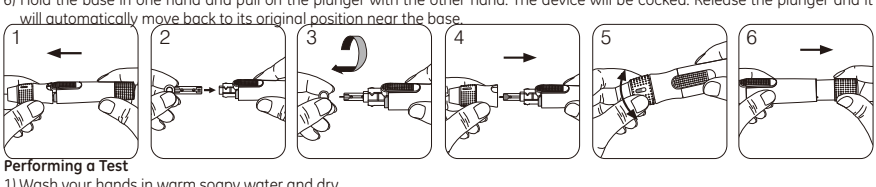
- Are intended for testing outside the body (in vitro diagnostic use for self-testing only).
- Are designed for use only with GE200 Blood Glucose Meter to assure accurate results.

Ge200 Blood Glucose Monitoring Systems includes meter, test strips, control solutions, lancing device and lancets.
Special conditions for use statement(s): GE200 Blood Glucose Monitoring System provides plasma equivalent results.

Test Procedure

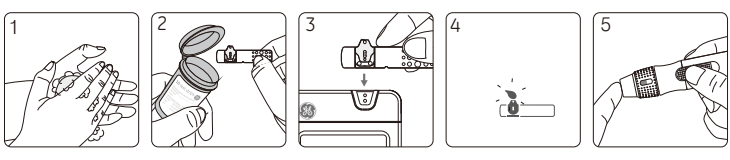
Preparing the Lancing Device

1) Pull off the depth adjustable cap.
2) Insert a new disposable lancet firmly into lancet carrier.
3) Twist off and set aside the protective cover of the disposable lancet.
4) Replace the depth adjustable cap.
5) Choose a depth of penetration by rotating the top portion of the depth adjustable cap until your desired setting is visible in the window. Settings are based on skin type: " " for soft or thin skin; " " for average skin; " " for thick or calloused skin.
6) Hold the base in one hand and pull on the plunger with the other hand. The device will be cocked. Release the plunger and it will automatically move back to its original position near the base.

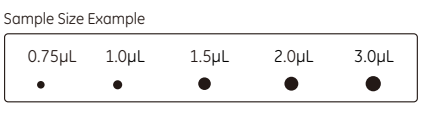


Performing a Test

1) Wash your hands in warm soapy water and dry.
2) Take one test strip from the vial. Close the vial cap immediately.
3) Insert the strip into the strip port of the meter with the sample window facing up. Push the strip in until it clicks and stops. The meter will automatically detect the code number.
4) When the blood drop icon flashes on the display window, blood sample is ready to be applied to the test strip port (apply within 2 minutes).
5) Place the lancing device to your fingertip and press the release button.



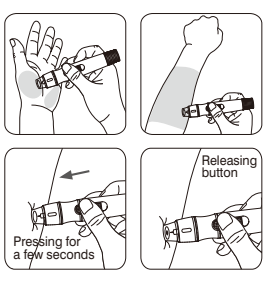
Sample Size Example



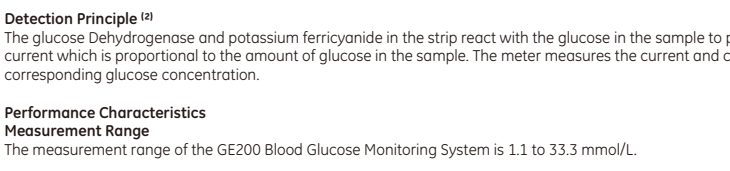
Please use a minimum blood drop size of 0.75μL to perform the test on glucose monitoring system. Blood drop sizes greater than 3.0μL are too large and may contaminate the test strip port of the meter.

Alternate site testing: palm or forearm blood sampling

- To perform a test using samples obtained from alternate sites, choose the clear cap and follow the steps above.
- Massage the intended puncture area of your palm or forearm for a few seconds.
- Immediately after massaging the area, press and hold the lancing device with the clear cap against your palm or forearm.
- Press the release button.
- Continue holding the lancing device against your palm or forearm and gradually increase pressure for a few seconds until the blood sample size is sufficient. (For more information on how to install the clear cap on the Lancing device, please refer to the Lancing Device instructions)
- DO NOT test on the palm or forearm if you are testing for hypoglycemia (low blood glucose).



6) Touch and hold the drop to the edge of sample port until you hear a " beep " (if volume is turned on) and the sample window is completely filled with blood. If the view window is not completely filled with blood the test will not start. If this is the case, discard the test strip and repeat the test with a new test strip.
7) The countdown mode will begin on the display window. After 5 seconds your test result will appear.
8) Remove the test strip from the meter. Please follow your local regulations to properly discard the used strip.
9) To remove the lancet, pull off the depth adjustable cap of the lancing device. Without touching the used disposable lancet, insert the lancet tip into the protective cover. Hold the release button of the lancing device in one hand and pull on the plunger with the other hand to safely eject the used disposable lancet into an appropriate puncture-proof or biohazard container.



For more information on how to use your meter and understand your test results, see the GE200 User's Manual.

Test Result

- Blood glucose test results are shown on the meter as mmol/L.
- If your blood glucose result is unusually high or low, or if you question your results, repeat the test with a new test strip. You can also run a Quality Control Test with the GE200 Control Solutions to check your meter and test strip. If the test result still remains unusually high or low, contact your Physician or the nearest Emergency Health Care Services immediately.
- If you are experiencing symptoms that are not consistent with your blood glucose test results and you have followed all the instructions in this insert, contact your Physician or the nearest Emergency Health Care Services immediately.
- The GE200 Blood Glucose Meter display results between 1.1 and 33.3 mmol/L. If your test result is below 1.1 mmol/L, " Lo " will appear on the screen. Please repeat your test with a new strip. If you still get a " Lo " result, you should immediately contact your Physician or the nearest Emergency Health Care Services.
- If your test result is above 33.3 mmol/L, " Hi " will appear on the screen. Please repeat your test with a new strip. If you still get a " Hi " result, you should immediately contact your Physician or the nearest Emergency Health Care Services.

Expected glucose values without diabetes [1]

Status	Range (mmol/L)
Fasting	< 5.6 mmol/L
Two hours after meals	< 7.8 mmol/L

Precautions

- Check the expiration date printed on the test strip vial. Do not use expired test strips.
- Close the test strip vial immediately after taking test strip out from the vial.
- Do not perform a control solution test with expired control solution.
- Do not bend or twist the test strip. A damaged test strip may cause incorrect test results.
- Do not reuse test strips.
- Do not reuse lancets. Discard used lancets properly.
- If the GE200 Blood Glucose Meter is exposed to a significant change in temperature, please wait at least 30 minutes before performing a test.
- If you want to purchase new control solutions, please contact *GE Diabetes* Customer Support Center at 1-866-613-7085.
- Test results may vary if blood samples are taken from different sites or under certain conditions where glucose levels can change rapidly such as: following a drink, a meal, an insulin dose or exercise. In these cases, only the fingertip should be used.
- Users should wash their hands thoroughly with soap and water after handling the meter, lancing device, control solution and test strips.
- The GE200 Blood Glucose Monitoring System should be cleaned and disinfected periodically (please refer to the GE200 Blood Glucose Monitoring System User's Manual for cleaning and disinfecting procedures).

Warning

- Keep the test strips and vial cap away from children; they may cause a choking hazard. If a test strip or vial cap is swallowed, contact your Physician immediately.
- All parts of the GE200 Blood Glucose Monitoring System are considered biohazardous and can potentially transmit infectious diseases, even after the cleaning and disinfecting procedures are followed.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple persons. Sharing them with others may increase the risk of blood borne pathogens transmission, such as hepatitis B transmission.

Limitations

- Blood glucose meter readings may be significantly lower than "true glucose levels" in a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested by the GE200 Blood Glucose Monitoring System, or if they are, they should be tested with extreme caution.
- Caution is advised when glucose values are below 2.8 mmol/L or above 13.9 mmol/L. Consult a Physician as soon as possible, if values in this range are obtained.
- Healthcare professionals should evaluate their technique and their patients' technique regarding the use of the GE200 Blood Glucose Monitoring System regularly. To accomplish this, it is recommended that blood glucose monitoring results be compared with a concurrently obtained laboratory measurement on the same blood sample. A proven clinical laboratory method employing hexokinase or glucose oxidase should be used as the comparative method.
- Hands and fingers contaminated with sugar from foods or beverages may cause falsely elevated results.
- The results of blood glucose measurements are different for measurements with whole blood and plasma.
- Storage of strips near bleach as well as bleach containing products will affect the results of the GE200 Test Strips.
- GE200 Test Strips are designed for use with capillary whole blood samples. Do not use serum or plasma samples.
- Inaccurate test results may be obtained at altitudes greater than 10,000 feet (3,048 meters) above sea level.
- Hematocrits below 10% may cause higher results. Hematocrits above 70% may cause lower results.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Do not perform the blood glucose test at temperatures below 43°F (6°C) or above 111°F (44°C), nor below 10% or above 90% relative humidity.
- Not for screening or diagnosis of diabetes mellitus.
- Inaccurate results may occur in severely hypotensive individuals or patients in shock.
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
- Not for neonatal use
- Alternate site testing should not be used to calibrate continuous glucose monitoring systems (CGMs).
- Alternate site testing should only be done during steady-state times (when glucose is not changing rapidly).
- Results from alternate site testing should not be used in insulin dose calculation.

NOTE
- Keep meter free of dust and liquids including water.

Storage and Handling

- Store the strips in the original capped vial at temperatures between 39 to 86°F (4°C to 30°C) and relative humidity below 90%. Do not freeze.
- Replace vial cap immediately and close lid tightly after removing a test strip. If the strip is exposed to the air too long, it will absorb the moisture and cause inaccurate test results.
- When you open a new vial of test strips please write the opening date on the label. Use test strips within 4 months after first opening or until the expiration date printed on the label (whichever comes first).

Quality Control

Please refer to the Quality Control section of the GE200 Blood Glucose Monitoring System User's Manual.

Troubleshooting and Customer Service

For more information on error messages and troubleshooting, please refer to the Error Messages and Troubleshooting section of the GE200 User's Manual.

You may also contact the *GE Diabetes* Customer Support Center by calling toll free at 1-866-613-7085 or by visiting our website at: www.gediabetes.com.

Additional Information for Healthcare Professionals

Detection Principle [2]

The glucose Dehydrogenase and potassium ferricyanide in the strip react with the glucose in the sample to produce an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration.

Performance Characteristics

Measurement Range

The measurement range of the GE200 Blood Glucose Monitoring System is 1.1 to 33.3 mmol/L.

Precision

The precision was evaluated with (i) venous whole blood sample (ii) 5 different glucose concentrations in 10 days by 10 meters.

(i) venous whole blood sample

Meters	P-01	P-02	P-03	P-04	P-05
(1) Mean (mmol/L)	2.0	5.0	7.2	12.2	18.4
(2) Total test numbers (n)	100	100	100	100	100
(3) SD (mmol/L)	0.10	0.08	0.12	0.21	0.29
(4) CV (%)	4.9%	1.7%	1.7%	1.7%	1.6%

(ii) Control solution

Glucose levels	CS-L	CS-N	CS-H
(1) Mean (mmol/)	2.8	5.6	16.7
(2) Total test numbers (n)	100	100	100
(3) SD (mmol/)	0.09	0.11	0.32
(4) CV (%)	3.4%	1.9%	1.9%

Accuracy

For the alternate site testing:

The accuracy of the alternate site test study of GE200 Blood Glucose Monitoring System was proved by comparing whole blood (plasma equivalent) glucose values on the GE200 Blood Glucose Meter with plasma glucose values on a YSI 2300 lab instrument. A total of 104 patients joined. A trained healthcare professional collected blood samples (from the fingertip, palm and forearm) with GE200 Blood Glucose Monitoring System. Another blood sample was collected within 5 minutes and was tested with plasma. Plasma was analyzed by the lab instrument. 98.9% of GE200 Blood Glucose Monitoring System values were within ± 15% of the YSI 2300 values at glucose concentrations ≧ 4.2 mmol/L and within ± 0.6 mmol/L at glucose concentrations < 4.2 mmol/L.
The results and variations between the two methods, GE200 Blood Glucose Monitoring System and YSI 2300 (as the reference method) are shown in the tables below.

Table 1: represents samples for glucose results lower than 4.2mmol/L.

Capillary samples collected from different testing sites	The percent (and number) of samples for which the difference between the GE200 Blood Glucose Meter value (Alternate site) and the YSI 2300 value were within the following intervals.		
	Within ± 0.3 mmol/L	Within ± 0.6 mmol/L	Within ± 0.8 mmol/L
Fingertip	(15/17) 88.2%	(17/17) 100.0%	(17/17) 100.0%
Palm	(13/17) 76.5%	(17/17) 100.0%	(17/17) 100.0%
Forearm	(14/17) 82.4%	(17/17) 100.0%	(17/17) 100.0%

Table 2: represents samples for glucose results greater than 4.2mmol/L.

Capillary samples collected from different testing sites	The percent (and number) of samples for which the difference between the GE200 Blood Glucose Meter value (Alternate site) and the YSI 2300 value were within the following intervals.			
	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Fingertip	(68/87) 78.2%	(85/87) 97.7%	(87/87) 100.0%	(87/87) 100.0%
Palm	(55/87) 63.2%	(84/87) 96.6%	(87/87) 100.0%	(87/87) 100.0%
Forearm	(53/87) 60.9%	(79/87) 90.8%	(86/87) 98.9%	(87/87) 100.0%

* Acceptance criteria in ISO15197 are that 95% of all differences in glucose values should be within ± 0.8mmol/L for glucose values less than 4.2mmol/L, and within ± 20% for glucose values greater than 4.2mmol/L.
Note: When glucose meter results are compared to the laboratory results, variation values below 4.2mmol/L are expressed in mmol/L, while those above 4.2mmol/L are compared in percent.

Interferences

High concentration of Xylose concentration (≧ 0.667 mmol/L), Uric acid (≧ 0.95 mmol/L), Ascorbic acid (≧ 0.166 mmol/L), Dopamine HCL (≧ 0.082 mmol/L) and L-Dopa (≧ 0.101 mmol/L) may result in inaccurate test results.

NOTE
- Acetaminophen, Ibuprofen, Methyldopa, Salicylic Acid, Tetracycline, Tolbutamide, Bilirubin-unconjugated, Cholesterol, Creatinine, Triglyceride, Maltose, Galactose and Lactose (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurate results.

Reagents

Each Blood Glucose Test Strip contains the following reagents:

Falvine-adenine dinucleotide-Glucose Dehydrogenase(FAD-GDH) (Aspergillus oryzae)	12.1%
Potassium ferricyanide	48.5%
Non-reactive ingredients	39.4%

References

1) *American Diabetes Association: Standard of Medical Care in Diabetes 2011, Diabetes Care*, vol.34, supplement 1, S11-S61, January 2011.
2) In Vitro Diagnostics in Diabetes : Meeting the Challenge. Clinical Chemistry 45:9, 1596-1601 (1999).